

REMARKS

Reconsideration of the present application is respectfully requested.

Claims 75-115 are pending in the application. Claims 75-78 are withdrawn. Claims 79 and 98 were amended to recite "up to 3 g of cocoa polyphenol per unit dose." Support for the amendment can be found in the specification, *e.g.*, at page 20 lines 17-18. No new matter was added.

Rejection under 35 USC Section 103

Claims 80-115 stand rejected as being obvious over Romanczyk, Jr. (US 5,554,645; hereinafter referred to as 'Romanczyk') in view of Wideman *et al.* (US 6,127,421; hereinafter referred to as 'Wideman') on the ground that a person of skill in the art would have been motivated to combine compounds/compositions of Romanczyk and Wideman because both are taught to be useful for the same purpose (anti-tumor) to form a third composition used for the same purpose. Applicants respectfully traverse the rejection.

The composition recited in the present claims is patentable over the combined teaching of Romanczyk and Wideman for the reasons explained below:

The Examiner is concerned that the present specification provides for very broad ranges of the compounds (*i.e.*, cocoa polyphenol and L-arginine) "so as to provide the effect of stimulating nitric oxide production, as well as arresting cancer cells" (Office Action, pages 6, lines 1-5). Applicants respectfully point out that claims now recite a specific maximum amount of cocoa polyphenol per unit dose of the product (*i.e.*, up to 3 g per unit dose of product). This numerical limitation must be considered and given due weight when examining the claims because the specific recited amounts would in fact create a structurally different composition so as to functionally limit it in terms of nitric oxide (NO) effects (*e.g.*, induction of vasorelaxation). As discussed in the present specification, the amounts of cocoa polyphenol and L-arginine recited in present claims

were found to be particularly preferred “to provide maximal benefit related to NO and NO-synthase modulation” and thus provide a “synergistic benefit” with respect to endothelium (NO) dependent vasodilation (see, specification p. 20, lines 4-9 and 15-18). The specific range of compounds as now recited in the claims is not suggested by the combination of Romanczyk and Wideman as discussed below.

The Examiner further states that the recited amounts of cocoa polyphenol and L-arginine “is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan” (Office Action, page 4, line 4-6). Applicants submit that it is well established under the US Patent Law that only result-effective variables can be optimized. MPEP Section 2144.05 II B. “A particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” *Id.* This is not the case here because the cited prior art fails to teach that the compounds cited in Applicant’s claims have nitric oxide effect; hence, in the absence of such a recognized result, arriving at the above quoted structural limitation of Applicants claims would not have amounted to routine optimization. It appears that the Examiner believes that the amounts recited in the present claims are the same as those recited in the cited art. However, the ranges of the combined amounts recited in the present claim are not suggested by the cited art and not having any knowledge of NO effect, a person of skill in the art would have had to conduct experimentation to arrive at them to first determine such NO effects, and then figure out the relevant ranges. There is no guidance or teaching along these lines in Romanczyk or Wideman. Moreover, claims 109 to 115, contain an entirely different range of L-arginine than disclosed in Wideman.

Thus, in view of the fact that Romanczyk nor Wideman alone or in combination fail to teach or disclose nitric oxide effect or vasodilation, a person of skill in the art would have not had any reasonable expectation of arriving at the Applicants’ present claims let alone knowing what numerical amounts of the recited compounds would have been effective for the recited function.

Finally, compositions recited in Applicants' claims provide an unexpected benefit, *i.e.*, they decrease arginase expression and activity. Applicants respectfully submit that they had previously pointed out this benefit (*see*, Amendment and Response filed December 16, 2008 and Attachments therein), however because the Examiner has neither acknowledged it nor commented on it, Applicants are uncertain as to whether the Examiner has considered it. Therefore, Applicants respectfully request the Examiner to consider the unexpected benefit argument which is briefly re-iterated below for the Examiner's convenience.

Thus, Applicants unexpectedly discovered that cocoa polyphenol and the polyphenolic compound of formula An recited in Applicants' claims not only beneficially modulate NO (*see*, specification, p. 20), but are also effective in reducing gene expression and activity of arginase (*see*, Amendment and response filed December 16, 2008, page 8, 1st full par.; par. spanning p. 8-9; p. 9, footnote1; and Attachment 1 (Schnorr *et al.*), of record). In other words, in the presence of cocoa polyphenol/polyphenol of formula A_n, more L-arginine becomes available for NO production due to reduced competition from arginase. This unexpected benefit is neither disclosed nor suggested by the cited prior art; withdrawal of the rejection is respectfully requested.

In view of the above amendments and remarks, withdrawal of the rejection is believed to be in order. An action to that effect is respectfully requested.

CONCLUSION

Applicants believe that the application is now in condition for allowance. A notice to that effect is respectfully requested.

Respectfully submitted,

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